Remarks/Arguments

This case has been reviewed and analyzed in view of the Official Action dated 7 November 2006.

The undersigned attorney acknowledges that Claims 11-14 have been allowed in the Official Action.

The Examiner has objected to dependent Claim 2 with regard to the term "the design limit of expansion". The Examiner has noted that there was no antecedent basis for this terminology and by this Amendment the terminology has been amended to read: "a design limit of expansion for the stent." The Examiner has also objected to Claim 14 with regard to the "plastic coating" having insufficient antecedent basis. Claim 14 has been amended to now show proper dependency upon Claim 13 which is believed to obviate the Examiner's objection.

The Examiner has rejected Claims 1-2 and 4-5 under 35 USC 103 as being obvious in view of the Roubin et al. Patent No. 5,827,321 reference. The Examiner contends that Roubin et al. shows a thin wall stent with a plurality of circumferential strut members with each of the strut members having strut elements with "curved sections" and "diagonal sections" as well as "flexible links."

The Examiner has admitted that the Roubin et al. does not disclose the inside area or perimeter of the cited reference stent.

It is respectfully submitted to the Examiner that for any stent being used for insertion into the human body within veins or arteries, the particular contouring of the stent is of extreme importance. The stents must be made extremely flexible for passage through tortuous passageways and must be substantially thin as to width for insert into the human blood vessel, while simultaneously having sufficient structural integrity to accept the loads imparted thereon.

Still further, the particular structure of the stents dictates that the stents must have a structural strength sufficient to accept folding of the stent in the undeployed state, while at the same time permitting the stent to be placed within a patients vessel and maintain its structural integrity during a deployed state.

With regard to Applicant's stent (and the Examiner's attention is particularly directed to Fig. 11), a stent 50 is provided which includes strut members 52P, 52D and 56 formed of strut elements with each of the strut elements having a diagonal section 58 and a curved section 53.

The curved sections 53 are continuous joined to the diagonal sections 58 and form a smooth arcuate curve for each of the strut elements of the strut members 56, 52P, 53D.

The flexible "M" or "W" links 54 must be joined on opposing ends thereof to the "curved sections" (element 53) on opposing ends in order to provide

flexibility in the longitudinal direction while simultaneously permitting structural integrity of the overall stent 50.

As can be clearly seen, the flexible links 54 are joined to the curved sections 53 wherein the curved sections 53 are continuously attached to the diagonal sections 58. This particular contouring allows for both the structural integrity as well as the flexibility necessary for stent 50.

In opposition, the Roubin et al. references is particularly directed to a intraluminal prosthesis or stent 40 which includes some type of curved segments 62 which are joined to "V" struts formed of sections 42, 44. Each pair of left and right struts 42/44 is connected at an "apex" 46 which forms a substantially "V-shape for the pair." This is shown on column 5, lines 32-36 of the Roubin et al. reference.

As further stated in the cited reference, the stent 40 of the Roubin et al. reference takes resemblance to a tubular lattice formed by the pairs of V-shaped struts 42/44 connected to themselves and having their apices 46 connected to the connecting members 48.

Opposingly the arcuate curved sections 53 being joined to the flexible links 54 in combination with the diagonal sections 58 of the subject application permit the combination of structural integrity and flexibility not found in the Roubin et al. reference.

In fact, it is not seen how the Roubin et al. reference can be folded in the manner shown without creating extensive stress at the apex points of the right/left struts during a folded state. Such causes extreme stress and may result in structural failure.

Thus, the Roubin et al. reference does not provide for: "...each strut element consisting of one curved section having a arcuate contour joined at a junction point to one diagonal section...", nor does it provide for: "...each of said flexible links being coupled to a respective strut member curve section on opposing ends of said flexible links...", as is necessary to now amended independent Claim 1. The Roubin et al. reference does not show the strut elements having a curve section in the nature of Applicant's disclosure nor does it show the flexible links being coupled on opposing ends to the curved sections of the strut member.

Still further, the Roubin et al. reference does not provide for: "...each strut element consisting of one curve section having an arcuate contour joined at the junction point to one diagonal section in a continuous manner...", as is necessary to now amended independent Claim 5. As previously noted, the Roubin et al. reference does not in fact show an arcuately contoured section but rather is directed to V-sections. Thus, the Roubin et al. reference further does not have: "...each flexible link having a proximal attachment point to a curved section of one circumferential set of strut members and a distal attachment point to a curved

section of a second circumferential set of strut members...", as is further necessary to now amended independent Claim 5.

The Examiner has further noted that the Roubin et al. reference does not teach the exact inside area or perimeter of the stent, but the Examiner feels that such would be obvious to one of ordinary skill in the art as is claimed in independent Claim 1 as amended and further in Claim 4.

Once again, it is noted to the Examiner that a stent, although having a few members, is critical in its contouring and structural connections to provide a system which has structural integrity within a vein, artery and vessel of a human being while simultaneously having the necessary flexibility for insertion. Thus, the sizing of the cells with regard to the perimeter is of importance in permitting the actual construction of the system. It is not obvious, even to one of ordinary skill in the art, that the perimeter cells must have a perimeter within a predetermined boundary. Thus, it is believed that the limitation provided in independent Claim 1 as amended wherein such states: "...the sets of strut members and connecting flexible links together forming a multiplicity of closed perimeter cells, at least half of all closed perimeter cells having an inside perimeter length greater than 9 mm", and the further limitation of Claim 4 as to the upper limit of the permitted length being 11 mm, is not obvious to one of ordinary skill in the art and further, is <u>not even addressed by the Roubin et al. reference</u> with regard to the

fabrication of his stent which does not take into account Applicant's limitations for the purposes and objectives as discussed.

With regard to the contouring, the Roubin et al. reference does not show" "...each individual flexible link having a maximum circumferential extent that is approximately the same as measured from each side of the link drawn between the proximal attachment point and the distal attachment point of that individual flexible link", as is necessary to Claim 5 as amended. It is not clear from the Roubin et al. reference whether any dimensional restrictions are imposed, however, such would be necessary in some manner to provide an operating system for the Roubin et al. reference where the combination of flexibility, and structural integrity are interwoven parameters.

Claims 2 and 4 are ultimately dependent on Claim 1 and are believed to show patentable distinction over the prior art as cited by the Examiner for at least the same reasons as previously discussed for the independent claims.

It is now believed that the subject patent application has been placed in condition for allowance and such action is respectfully requested.

Respectfully submitted,
FOR: ROSENBERG, KLEIN & LEE

Morton J. Rosenberg
Registration No. 26,049

Dated: 2/6/07

Suite 101
3458 Ellicott Center Drive
Ellicott City, MD 21043
Tel: 410-465-6678

Customer No.
04586